

WHAT IS CLAIMED IS:

1. A surgical device for holding esophageal tissue during a fundoplication procedure, comprising:
 - a proximal member having a vacuum port connectable to a source of vacuum;
 - a substantially flexible conduit having a proximal end connected to the proximal member, the conduit having a lumen in fluid communication with the source of vacuum; and
 - a distal member connected to a distal end of the conduit and configured to hold the esophageal tissue when suction is supplied to the vacuum port from the source of vacuum.
2. A surgical device according to claim 1, wherein the distal member defines at least one suction opening through which the esophageal tissue is to be held.
3. A surgical device according to claim 2, wherein the at least one suction opening includes a plurality of suction openings arranged about the distal member.
4. A surgical device according to claim 1, wherein the distal member comprises an elongate, curved plate and a concave insert, the plate and the insert engaged to form a space therebetween.
5. A surgical device according to claim 4, wherein the elongate plate defines at least one suction opening through which the esophageal tissue is to be held.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

6. A surgical device according to claim 5, further comprising means for grasping the esophageal tissue held by the suction, the means for grasping the esophageal tissue disposed proximate the suction opening.
7. A surgical device according to claim 1, further comprising means for grasping the esophageal tissue held by the suction.
8. A surgical device according to claim 7, further comprising a controller for controlling the means for grasping the esophageal tissue.
9. A surgical device according to claim 7, wherein the means for grasping the esophageal tissue includes a jaw assembly.
10. A surgical device according to claim 9, wherein the jaw assembly includes a pair of jaws attached to a flexible member such that the pair of jaws move toward each other when the flexible member is deformed.
11. A surgical device according to claim 10, wherein the jaw assembly further includes an actuation device configured to deform the flexible member.
12. A surgical device according to claim 11, wherein the actuation device comprises a cable extending from the distal member to the proximal member, the cable attached to an axially movable member of the proximal member, such that an axial movement of the movable member causes the flexible member to deform.
13. A surgical device according to claim 12, further comprising a rotating member for causing the axial movement of the movable member.
14. A surgical device according to claim 1, wherein the distal member comprises a tubular member having at least one suction cup on an outer surface of the

tubular member, the suction cup being in fluid communication with the source of vacuum.

15. A surgical device according to claim 14, wherein the tubular member is radially expandable.
16. A surgical device according to claim 1, further comprising means for actuating the source of vacuum.
17. A surgical device according to claim 1, wherein at least a portion of the device is coated with polymer or elastomer material.
18. A surgical device for invaginating esophageal tissue of a body, comprising:
 - an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the esophageal tissue of the body; and
 - a distal member coupled to the distal end of the tube, the distal member including a projection configured to engage the esophageal tissue.
19. A surgical device according to claim 18, wherein the distal member comprises:
 - a tubular body having at least one side opening; and
 - a needle having the projection, the needle disposed inside the tubular body and configured to extend out of the tubular body through the side opening, the projection being a barbed distal end.
20. A surgical device according to claim 18, wherein the distal member comprises:
 - a proximal portion and a distal portion,
 - an actuation member for axially moving the proximal portion and the distal portion relative to each other;

a plurality of flexible wires connecting the proximal portion and the distal portion, each of the wires configured to bend radially outwardly when the proximal and distal portions are moved relative to each other, wherein each of the wires includes the projection.

21. A surgical device for invaginating esophageal tissue of a body, comprising:
- an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the esophageal tissue of the body; and
 - a distal member coupled to the distal end of the tube, the distal member including a friction member for frictionally engaging the esophageal tissue.
22. A surgical device according to claim 21, wherein the distal member comprises:
- a proximal portion and a distal portion;
 - an actuation member for axially moving the proximal portion and the distal portion relative to each other; and
 - a plurality of flexible wires connecting the proximal portion and the distal portion, each of the wires configured to bend radially outwardly to frictionally engage the esophageal tissue when the proximal and distal portions are moved toward each other.
23. A surgical device according to claim 21, wherein the friction member includes a radially expandable tubular member.
24. A surgical device according to claim 21, wherein the friction member includes an axially extendable, bellow-shaped tubular member having a plurality of

frictionally engaging member configured to radially extend and engage the esophageal tissue when the tubular member is contracted axially, the tubular member forms a substantially straight outer profile when the tubular member is extended axially.

25. A surgical device according to claim 21, wherein the friction member includes a tubular body formed of braided wire, the tubular body being radially expandable to frictionally engage the esophageal tissue.
26. A surgical device according to claim 25, wherein at least a portion of the tubular body includes a projection extending radially outwardly with respect to outer surface of the tubular body.
27. A surgical device according to claim 21, wherein the friction member includes a plurality of wires interconnected to form an expandable anchor configured to frictionally engage the esophageal tissue in an expanded state.
28. A surgical device according to claim 27, wherein at least one of the wires includes a projection extending radially outwardly with respect to outer surface of the expandable anchor.
29. A surgical device for invaginating tissue of a first organ into a second organ in a body, comprising:
 - an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the tissue of the first organ; and
 - a distal member coupled to the distal end of the tube and configured to extend beyond the tissue to be invaginated and into the second organ,

the distal member including an expandable portion for applying a force to tissue of the second organ and thereby invaginate the tissue of the first organ into the second organ.

30. A surgical device according to claim 29, wherein the expandable portion of the distal member is a balloon.
31. A surgical device according to claim 29, further comprising means for holding tissue proximal to the tissue of the first organ to be invaginated.
32. A surgical device according to claim 31, wherein the means for holding the proximal tissue is a radially expandable balloon.
33. A surgical device according to claim 31, wherein the means for holding the proximal tissue is a grasper.
34. A device for displacing tissue of a body, comprising:
 - an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the tissue; and
 - a distal member coupled to the distal end of the tube and having at least one rotating member, the rotating member configured to contact the tissue layer and displace the tissue in the rotating direction.
35. A surgical device for displacing tissue of a body, comprising:
 - an elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the tissue; and
 - a distal member coupled to the distal end of the tube and having a rotatable arm configured to rotate relative to the axis of the tube,

wherein at least one end of the rotatable arm is configured to contact the tissue when the rotatable arm rotates relative to the axis of the tube.

36. A surgical device according to claim 35, wherein the at least one end of the rotatable arm comprises a sharp edge.
37. A surgical device according to claim 35, further comprising an actuating member for rotating the rotatable arm.
38. A surgical device for grasping esophageal tissue of a body, comprising:
 - a flexible elongated tube having a proximal end configured to extend outside of the body and a distal end configured to extend proximate the esophageal tissue of the body; and
 - a distal member coupled to the distal end of the tube and having at least one forceps to grasp the esophageal tissue.
39. A surgical device according to claim 38, wherein the distal member comprises:
 - a tubular body having at least one opening; and
 - a flexible wire having the forceps coupled to the distal end of the wire, the wire extendable through the opening to grasp the tissue.
40. A surgical device according to claim 38, wherein the forceps is rotatably coupled to the distal member.
41. A method of invaginating tissue toward an organ having an opening, comprising:
 - inserting an elongated tubular member into a body passage so that a distal end of the tubular member is proximate the tissue;
 - contacting the tissue with the distal end; and

displacing the tissue toward the opening of the organ by displacing the distal end of the member.

42. A method according to claim 41, wherein contacting the tissue comprises holding the tissue by suction.
43. A method according to claim 42, further comprising supplying a source of vacuum to the distal end through the tubular member.
44. A method according to claim 42, wherein holding the tissue includes holding the tissue through a suction opening of the distal end of the tubular member.
45. A method according to claim 42, wherein the distal end of the tubular member comprises an elongate, curved plate and a concave insert, the plate and the insert engaged to form a space therebetween.
46. A method according to claim 45, wherein the elongate plate defines at least one suction opening through which the tissue is to be held.
47. A method according to claim 42, wherein contacting the tissue further comprises grasping the tissue held by suction.
48. A method according to claim 47, wherein grasping the tissue includes grasping the tissue with a pair of jaws.
49. A method according to claim 48, further comprising actuating the pair of jaws by a cable extending from the distal end to the proximal end of the tubular member.
50. A method according to claim 42, wherein holding the tissue by suction includes holding the tissue with at least one suction cup on an outer surface of the distal end.

51. A method according to claim 50, further comprising radially expanding the distal end.
52. A method according to claim 41, wherein contacting the tissue comprises grasping the tissue by frictionally engaging the tissue.
53. A method according to claim 52, wherein the distal end comprises:
- a tubular body having at least one side opening; and
 - a needle having a barbed distal end disposed inside the tubular body and configured to extend out of the tubular body through the side opening, wherein frictionally engaging the tissue comprises extending the needle out of the tubular body.
54. A method according to claim 52, wherein the distal end comprises:
- a tubular body having a proximal portion and a distal portion;
 - an actuation member for axially moving the proximal portion and the distal portion relative to each other; and
 - a plurality of flexible wires connecting the proximal portion and the distal portion, each of the wires configured to bend radially outwardly when the proximal and distal portions are moved toward each other, each of the wires includes a friction member,
- wherein frictionally engaging the tissue comprises moving the proximal and distal portions toward each other.
55. A method according to claim 54, further comprising providing a projection extending outwardly from each wire.

56. A method according to claim 52, further comprising providing at least one projection extending outwardly from the outer surface of the distal end.
57. A method according to claim 52, wherein the distal end of the tubular member is radially expandable, wherein frictionally engaging the tissue comprises holding the tissue by radially expanding the distal end.
58. A method according to claim 52, wherein:
- the distal end of the tubular member includes an axially extendable, bellow-shaped tubular portion having a plurality of the friction members;
 - the friction members of the tubular portion are configured to radially extend and contact the tissue when the tubular portion is contracted axially, and the tubular portion forms a substantially straight outer profile when the tubular portion is extended axially; and
 - frictionally engaging the tissue comprises contracting the tubular portion axially.
59. A method according to claim 52, wherein the distal end of the tubular member includes a tubular body formed of braided wire, the tubular body being radially expandable, wherein frictionally engaging the tissue comprises radially expanding the tubular body.
60. A method according to claim 59, wherein at least a portion of the tubular body includes a projection extending outwardly from the tubular body.
61. A method according to claim 52, wherein the distal end includes a plurality of wires interconnected to form an expandable anchor, wherein frictionally engaging the tissue comprises expanding the plurality of wires.

62. A method according to claim 41, wherein the distal end of the tubular member comprises at least one forceps to hold the tissue, wherein contacting the tissue comprises grasping the tissue by the at least one forceps.
63. A method according to claim 62, wherein the forceps is rotatably coupled to the distal end.
64. A method according to claim 62, further comprising:
providing at least one opening in the distal end;
providing a flexible wire having the forceps coupled to a distal end of the wire; and
extending the wire having the forceps through the opening to grasp and hold the tissue.
65. A method according to claim 41, wherein contacting the tissue layer comprises holding the tissue layer by a needle.
66. A method according to claim 41, wherein the distal end of the tubular member comprises at least one rotating member configured to contact the tissue, wherein contacting the tissue comprises bringing the rotating member in contact with the tissue and displacing the tissue comprises rotating the at least one rotating member.
67. A method according to claim 41, wherein the distal end of the tubular member comprises a rotatable arm configured to rotate relative to the axis of the tubular member, at least one end of the rotatable arm configured to contact the tissue when the rotatable arm rotates relative to the axis of the tube, wherein contacting the tissue comprises rotating the rotatable arm.

68. A method according to claim 67, wherein at least one end of the rotatable arm comprises a sharp edge.
69. A method according to claim 41, wherein the tissue is esophageal tissue and the organ is a stomach.
70. A method according to claim 41, wherein the displacing the tissue layer includes stretching the tissue proximate to the tissue to be invaginated.
71. A method according to claim 70, further comprising:
- extending the distal end of the tubular member beyond the tissue to be invaginated into the opening of the organ, the distal end including an expandable portion for applying a force to stretch a tissue of the organ and thereby invaginate the tissue toward the opening of the organ, and expanding the expandable portion to invaginate the tissue to be invaginated toward the opening of the organ.
72. A method according to claim 69, wherein the expandable portion of the distal end is a balloon.
73. A method according to claim 71, further comprising holding tissue proximal to the tissue to be invaginated prior to expanding the expandable portion.
74. A method according to claim 73, wherein the tissue proximal to the tissue to be invaginated is held by a radially expandable balloon.
75. A device to cover a distal end of an endoscopic instrument, the device comprising:
- a distal tube having a lumen sized to receive an endoscope;
 - an inflatable member coupled to the distal tube;

a sleeve configured to cover the distal end of the endoscopic instrument, the inflatable member covering a distal end of the sleeve; and a tube having an inflation lumen in fluid communication with the inflatable member.

76. The device of claim 75, wherein the tube includes an actuation lumen having an actuator.
77. The device of claim 76, wherein the actuator is a wire that includes a loop portion surrounding the sleeve.
78. The device of claim 77, wherein the wire is configured so that pulling proximally on the wire closes the loop portion on the sleeve.
79. The device of claim 75, wherein the inflatable member is a balloon.
80. The device of claim 75, wherein the inflatable member is fixed to the sleeve along a circumference of the sleeve.
81. The device of claim 75, wherein the inflatable member surrounds at least a portion of the distal tube.
82. A method of inserting an endoscopic instrument into a tissue tract of a patient, the method comprising:

placing a protective device over a distal end of the endoscopic instrument, the protective device including a sleeve to cover the distal end of the endoscopic instrument and an inflatable member covering a distal end of the sleeve;

inflating the inflatable member; and

inserting the endoscopic instrument into the tissue tract of the patient with the inflatable member inflated.

83. The method of claim 82, further comprising inserting an endoscope through the sleeve and the inflatable member.
84. The method of claim 83, wherein the protective device includes a distal tube having a lumen sized to receive the endoscope.
85. The method of claim 82, further comprising removing the protective device from the endoscopic instrument.
86. The method of claim 82, wherein removing the protective device includes pulling the protective device proximally through a channel of the endoscopic instrument.
87. The method of claim 82, wherein removing the protective device includes inverting the sleeve.
88. The method of claim 87, wherein removing the protective device includes inverting the inflatable member.
89. The method of claim 82, further comprising advancing the sleeve distally after the endoscopic instrument is positioned at a desired location.
90. The method of claim 89, further comprising actuating an actuator to substantially close the sleeve after advancing the sleeve distally.
91. The method of claim 90, wherein the actuator includes a wire having a loop portion surrounding the sleeve.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com